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REMARKS

Formal Matters

Claims 17-36 are pending.

Claims 17-26, 30 and 32 were examined and rejected.

Claims 17 and 32 are amended for clarity. No new matter is added.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Interview Summary

Examiners Wessendorf and Schultz are thanked for the telephonic interview with Applicants' representatives James Keddie, Carol Francis and James Diehl on December 1, 2006.

All rejections were discussed. No agreements were reached during this interview.

In a subsequent telephone interview with Exr. Shultz and James Keddie on December 20, 2006, Exr. Shultz stated that:

a) the rejections under 35 U.S.C. § 112, second paragraph, would be withdrawn by making clarifying statements on the record;

b) the rejection under 35 U.S.C. § 102 would be withdrawn if the cited prior art (Nolan) fails to explicitly disclose each and every element of the rejected claims; and

c) the rejections under 35 U.S.C. § 103(a) could be withdrawn via 35 USC § 103(c), as modified by the CREATE Act of 2004.

Submitted herewith are Exhibit A (showing a timeline of events), Exhibit B (a copy of an assignment of Nolan II (6,153,380) to Rigel in October 1997), Exhibit C (a copy of an assignment of the instant application to Rigel in June 1998) and Exhibit D (showing the claims of Nolan I (6,455,247) and Nolan II), as presented during the interview of December 1, 2006.

Request for Interview

Exr. Wessendorf is invited to telephone James Keddie at (650) 833 7723 to arrange an interview with Exrs. Wessendorf and Schultz if any issues remain if or this response fails to yield a Notice of Allowance.

Restriction/Election

The Examiner is again reminded that upon election of a species for initial examination, the Examiner's actions must conform to MPEP §809.02(c). If the generic claim, in this case claim 17, is allowable, the election of species must be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

If the Applicants understand this rejection correctly, the Examiner argues that the claims are indefinite because: 1) it is not clear whether the library of retroviral vectors is contained by a cell or a population of cells; 2) it is unclear if the sorting step is done using at least five parameters; 3) the term "expression of a receptor gent" is not understandable in claim 1; and 4) claim 32 assertedly fails to limit the subject matter for claim 17.

In accordance with Exr. Shultz' advice during the aforementioned interviews, the Applicants hereby respond to the first two parts of this rejection by placing clarifying statements on the record. Namely, the Applicants submit that: a) it would be apparent from the specification that the library of retroviral vectors is contained by a population of cells, rather than a single cell; and b) it would apparent from the claims that the population of cells is sorted using at least five parameters.

Claims 1 and 32 have been amended and, as such, it is believed that the third and fourth aspects of this rejection are now moot.

The Applicants believe that this rejection has been addressed. Withdrawal of this rejection is requested.

Obviousness-type double patenting

Claims of this application are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patents 6,461,813 and 6,897,031.

The Applicants categorically disagree with this rejection.

However, solely to expedite prosecution, the Applicants provide herewith a Terminal Disclaimer over US patents 6,461,813 and 6,897,031.

The Applicants note that the filing of a Terminal Disclaimer to obviate a rejection based on non-statutory double patenting is not an admission of the propriety of the rejection.[1] As such, while the Applicants firmly believe that this rejection fails to meet the requirements for Obviousness-Type Double Patenting set forth in MPEP § 804, a Terminal Disclaimer is nevertheless filed.

Withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. § 102 - Nolan

Claims 17-24, 30 and 32 are rejected under 35 U.S.C. § 102(e) as anticipated by Nolan (U.S. 6,455,247). The Applicants respectfully traverse this rejection.

It is well established that a claim is anticipated only if each and every element of the claim is set forth in a single prior art reference.[2]

The rejected claims recite an element that includes sorting a population of cells using *at least five* FACS parameters. The Applicants submit that Nolan fails to explicitly disclose any method that includes sorting cells using at least five FACS parameters. As such, Nolan cannot anticipate the rejected claims and this rejection should be withdrawn.

If the Examiner believes that this rejection should be maintained, the Examiner is requested to: a) identify where in Nolan's disclosure a method that includes sorting cells on at least *five* FACS parameter

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[1] *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). The court indicated that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection."

[2] MPEP § 2131: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)

is disclosed, and b) confer with Exr. Schultz about maintaining the rejection, prior to mailing of the next Office Action.

Rejection under 35 U.S.C. § 103

Claims 17-25, 30 and 32 are rejected under 35 U.S.C. § 103 as obvious over U.S. Patent No. 6,455,247 (hereinafter "Nolan I") in view of Jia-Ping or Ryan. Claim 26 is rejected under 35 U.S.C. § 103 as obvious over Nolan I in view of Jia-Ping or Ryan and Hide. The Applicants respectfully traverse these rejections.

Each of these rejections is based on Nolan I, which is citable only under § 102(e) and therefore potentially disqualified under § 103(c)[3].

The subject matter relied upon by the Examiner to establish this rejection relates to a method in which a random peptide library is introduced into cells, and the cells are screened for a phenotype. For the sake of brevity, this method is called "Nolan's intracellular random peptide screening method".

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[3] 35 USC § 103(c):

(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

(2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if -

(A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(3) For purposes of paragraph (2), the term "joint research agreement" means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

Applying 35 U.S.C. § 103(c)(1), this rejection should be withdrawn if the Applicants can show that Nolan's intracellular random peptide screening method was owned by Rigel before the earliest priority date of the instant application. The Applicants submit that Nolan's intracellular random peptide screening method was owned by Rigel before the earliest priority date of the instant application and, as such, this rejection should be withdrawn. Support for the Applicant's position is set forth below.

Nolan's intracellular random peptide screening method was claimed in 09/789,333 (now U.S. Patent No. 6,153,380 and referred to as "Nolan II" herein. Nolan II was assigned to Rigel on October 14, 1997, which is well before the earliest priority date of the instant application (April 17, 1998)[4]. Nolan I claims an entirely different method to that claimed in Nolan II.[5]

Thus, the subject matter relied upon to establish this rejection (i.e., Nolan's *intracellular* random peptide screening method) was assigned to Rigel at the time of filing of this present application. As such, this rejection may be withdrawn via 35 U.S.C. § 103(c)(1).

Nevertheless, given the advice of Exr. Shultz in the aforementioned telephonic interview of December 20, 2006, the Applicants submit herewith the following items:

a) a Request for Continued Examination;

b) a statement under 37 CFR § 1.104(c)(4) indicating that the subject matter of the rejected claims was made as a result of activities undertaken within the scope of a joint research agreement between Stanford University and Rigel Pharmaceuticals; and

c) an amendment to the specification indicating the names of the parties to the joint research agreement.

Given these items, the Applicants submit that these rejections may be withdrawn via the CREATE Act of 2004, i.e., 35 U.S.C. § 103(c)(2).

In view of the foregoing discussion, this rejection may be withdrawn.

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[4] Evidence of assignment of Nolan II to Rigel is submitted as Exhibit B.

[5] Exemplary claims of Nolan I and Nolan II are submitted as Exhibit D. Claim 1 of Nolan I is directed to unrelated "cocultivation" methods which in which FACS cannot be used to isolate the cells containing the bioactive peptide. In contrast, claim 1 of Nolan II, which fairly represents the subject matter used to establish this rejection, is directed to intracellular peptide screening methods. Nolan II was assigned to Rigel at the filing date of the instant application

Again, if there is any reason why the Examiner believes that this rejection should be maintained, she is requested to confer with Exr. Schultz prior to mailing of the next Office Action. As noted above, a telephonic interview with Exrs. Wessendorf and Schultz is requested if the Examiner believes that this rejection should be maintained in light of the above.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RIGL-036CIP.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: January 8, 2007

By: _____
James S. Keddie, Ph.D.
Registration No. 48,920

Enclosures: Terminal Disclaimer over US patents 6,461,813 and 6,897,031
Exhibit A: timeline of events
Exhibit B: assignment of Nolan II (6,153,380) to Rigel in October 1997
Exhibit C: assignment of the instant application to Rigel in June 1998
Exhibit D: claims of Nolan I (6,455,247) and Nolan II (6,153,380)

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, CA 94303
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EXHIBIT A - timeline

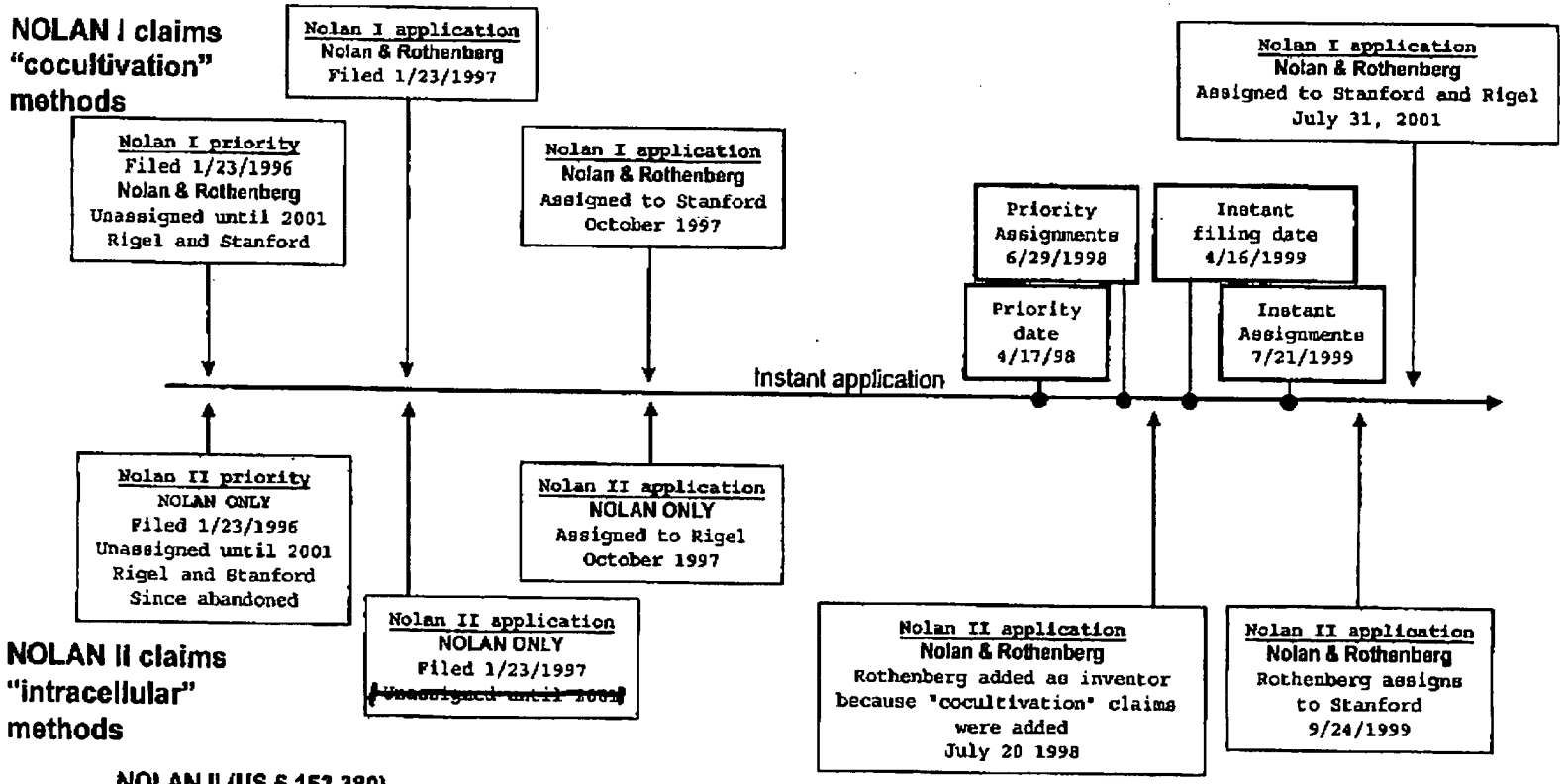
NOLAN I (US 6,455,247); cited in Office Action

Nolan I specification identical to Nolan II

Nolan I claims "cocultivation methods" that are not related to the subject matter cited by the Examiner.

Nolan II's cocultivation methods could not be cited to render the instant claims obvious because the cells with the phenotype do not contain the bioactive peptide (i.e., aren't "intracellular methods).

Nolan I was assigned to Stanford prior to the earliest priority date of the instant application



NOLAN II (US 6,153,380)

Nolan II specification is identical to Nolan I

Nolan II claims "intracellular methods" - it is these methods that are used by the Examiner

Nolan II was assigned to Rigel prior to the earliest priority date of the instant application

We believe that Nolan was obligated to assign to Rigel.

We believe that Rothenberg was obligated to assign to Stanford.

FILE

EXHIBIT B - 09/062,330 assignment

Attorney Docket No.: A-65688/DJB/RMS/DAV

ASSIGNMENT

WHEREAS, the undersigned, **Joseph Fisher**, 2634 Belmont Canyon Road, Belmont, CA; **James Lorens**, 2010 Avy Avenue, Menlo Park, CA; **Donald Payan**, 24 Windsor Drive, Hillsborough, CA and **Alexander Rossi**, 2177 - 48th. Avenue, San Francisco, CA (hereinafter termed "Inventors"), have invented certain new and useful improvements in MULTIPARAMETER FACS ASSAYS TO DETECT ALTERATIONS IN EXOCYTOSIS and have executed concurrently herewith an application for a United States patent disclosing and identifying the invention; and having Serial No. 09/062,330 and filing date of 17 April 1998 and

WHEREAS, Rigel Pharmaceuticals, Inc. (hereinafter termed "Assignee"), a corporation of the State of California, having a place of business at 772 Lucerne Drive, Sunnyvale, State of California, is desirous of acquiring the entire right, title and interest in and to said application and the invention disclosed therein, and in and to all embodiments of the invention, heretofore conceived, made or discovered by said Inventors (all collectively hereinafter termed "said invention"), and in and to any and all patents, inventors' certificates and other forms of protection (hereinafter termed "patents") thereon granted in the United States and foreign countries.

NOW, THEREFORE, in consideration of good and valuable consideration acknowledged by said Inventors to have been received in full from said Assignee:

1. Said Inventors do hereby sell, assign, transfer and convey unto said Assignee, the entire right, title and interest (a) in and to said application and said invention; (b) in and to all rights to apply for foreign patents on said invention pursuant to the International Convention for the Protection of Industrial Property or otherwise; (c) in and to any and all applications filed and any and all patents granted on said invention in the United States or any foreign country, including each and every application filed and each and every patent granted on any application which is a division, substitution, or continuation of any of said applications; and (d) in and to each and every reissue or extensions of any of said patents.

2. Said Inventors hereby covenant and agree to cooperate with said Assignee to enable said Assignee to enjoy to the fullest extent the right title and interest herein conveyed in the United States and foreign countries. Such cooperation by said Inventors shall include

prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said Assignee (a) for perfecting in said Assignee the right, title and interest herein conveyed; (b) for prosecuting any of said applications; (c) for filing and prosecuting substitute, divisional, continuing or additional applications covering said invention; (d) for filing and prosecuting applications for reissuance of any said patents; (e) for interference or other priority proceedings involving said invention; and (f) for legal proceedings involving said invention and any applications therefor and any patents granted thereon, including without limitation opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said Inventors in providing such cooperation shall be paid for by said Assignee.

3. The terms, covenants and conditions of this assignment shall inure to the benefit of said Assignee, its successors, assigns and other legal representatives, and shall be binding upon said Inventors, their heirs, legal representatives and assigns.

4. Said Inventors hereby warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

IN WITNESS WHEREOF, the said Inventors have executed and delivered this instrument to said Assignee.

By Joseph Fisher
Joseph Fisher

County of Santa Clara)
) ss.
State of Calif.)

On this 29 day of June, in the year 1998, before me, Patricia A. Gaster Notary Public of the State of Calif., personally appeared Joseph Fisher, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person whose name is subscribed to the within instrument, and acknowledged to me that he/she executed the same in his/her authorized capacity(ies), and that by his/her signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.

Signature Patricia A. Gaster (Seal)

Attorney Docket No.: A-65688/DJ8/RMS/DAV

By James Lorens
James Lorens

County of Santa Clara .)
) ss.
State of California .)

On this 25 day of June, in the year 1998, before me, Tanya M Lacha Notary Public of the State of CA, personally appeared James Lorens, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person whose name is subscribed to the within instrument, and acknowledged to me that he/~~she~~ executed the same in his/~~her~~ authorized capacity(~~ies~~), and that by his/~~her~~ signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.

Signature Tanya M. Lacha

TANYA M. LAEHA
Commission # 1154269
Notary Public — California
Santa Clara County
My Comm. Expires Sep 5, 2001

(Seal)

By Donald G. Payan
Donald Payan

County of Santa Clara .)
) ss.
State of California .)

On this 25 day of June, in the year 1998, before me, Tanya M Lacha Notary Public of the State of CA, personally appeared Donald Payan, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person whose name is subscribed to the within instrument, and acknowledged to me that he/~~she~~ executed the same in his/~~her~~ authorized capacity(~~ies~~), and that by his/~~her~~ signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.

Signature Tanya M. Lacha

TANYA M. LAEHA
Commission # 1154269
Notary Public — California
Santa Clara County
My Comm. Expires Sep 5, 2001

(Seal)

Attorney Docket No.: A-65688/DJB/RMS/DAV

By _____
Alexander Rossi

County of Santa Clara .)
) ss.
State of California .)

On this 25 day of June, in the year 1998, before me, Tanya M. Lasha Notary Public of the State of CA, personally appeared Alexander Rossi, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person whose name is subscribed to the within instrument, and acknowledged to me that he executed the same in his authorized capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.

Signature Tanya M. Lasha (Seal)

TANYA M. LASHA
Commission # 1154269
Notary Public — California
Santa Clara County
My Comm. Expires Sep 5, 2001

EXHIBIT C – 08/789,333 "NOLAN II" assignment

ASSIGNMENT

(NOT ACCOMPANYING APPLICATION)

WHEREAS, the undersigned, Garry P. Nolan , (hereinafter termed "Inventor"), of Menlo Park County of San Mateo, State of California has invented certain new and useful improvements in METHODS FOR SCREENING FOR TRANSDOMINANT EFFECTOR PEPTIDES AND RNA MOLECULES, and have executed an application for a United States patent disclosing and identifying the invention on even date herewith; and having Serial No. 08/789,333 and filing date of 23 January 1997; and

WHEREAS, Rigel Pharmaceuticals, Inc. A corporation of the State of California, having a place of business at 772 Lucerne Drive, Sunnyvale, State of California, (hereinafter termed "Assignee"), is desirous of acquiring the entire right, title and interest in and to said application and the invention disclosed therein, and in and to all embodiments of the invention, heretofore conceived, made or discovered jointly or severally by said inventors (all collectively hereinafter termed "said invention"), and in and to any and all patents, inventor's certificates and other forms of protection (hereinafter termed "patents") thereon granted in the United States and foreign countries.

NOW, THEREFORE, in consideration of good and valuable consideration acknowledged by said inventors to have been received in full from said Assignee:

1. Said inventors do hereby sell, assign, transfer and convey unto said Assignee, the entire right, title and interest (a) in and to said application and said invention; (b) in and to all rights to apply for foreign patents on said invention pursuant to the International Convention for the Protection of Industrial Property or otherwise; (c) in and to any and all applications filed and any and all patents granted on said invention in the United States or any foreign country, including each and every application filed and each and every patent granted on any application which is a division, substitution, or continuation of any of said applications; and (d) in and to each and every reissue or extensions of any of said patents.

2. Said inventors hereby jointly and severally covenant and agree to cooperate with said Assignee to enable said Assignee to enjoy to the fullest extent the right title and interest herein conveyed in the United States and foreign countries. Such cooperation by said inventors shall include prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said Assignee (a) for perfecting in said Assignee the right, title and interest herein conveyed; (b) for prosecuting any of said applications; (c) for filing and prosecuting substitute, divisional, continuing or additional applications covering said invention; (d) for filing and prosecuting applications for reissuance of any said patents; (e) for interference or other priority proceedings involving said invention; and (f) for legal proceedings involving said invention and any applications

therefor and any patents granted thereon, including without limitation opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said Inventors in providing such cooperation shall be paid for by said Assignee.

3. The terms and covenants of this assignment shall inure to the benefit of said Assignee, its successors, assigns and other legal representatives, and shall be binding upon said Inventors, their respective heirs, legal representatives and assigns.

4. Said Inventors hereby jointly and severally warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

IN WITNESS WHEREOF, the said Inventors have executed and delivered this instrument to said Assignee as follows:

Date: 10/14/92

Garry P. Nolan

County of Santa Clara)
) ss. 090-64-8248
State of CT)

On this ___ day of _____, in the year ___, before me, _____, Notary Public of the State of _____, personally appeared (1) **Garry P. Nolan**, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person whose name is subscribed to the within instrument, and acknowledged that he/she executed the same in his/her authorized capacity(ies), and that by his/her signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.

Signature _____ (Seal)

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Exhibit A

Claim 1 from Nolan I (6,455,247). Nolan I's claims relate to *intercellular* screening methods in which FACS cannot be employed to isolate cells containing the bioactive peptide.

> We claim:
> 1. A method of screening for a transdominant bioactive agent that alters the phenotype of a cell, said method comprising the steps:
> a) introducing a molecular library of randomized candidate nucleic acids, each operably linked to nucleic acid encoding a secretion signal, into a first plurality of cells, wherein each of said nucleic acids comprises a different nucleotide sequence, wherein said randomized candidate nucleic acids are expressed in said first cells to produce a plurality of randomized peptides; and
> b) screening a second plurality of cells which are co-cultured with said first plurality of cells for a cell exhibiting an altered phenotype, wherein said altered phenotype is due to the presence of a transdominant bioactive agent.

Claim 1 from Nolan II (U.S. 6,153,380). The subject matter of Nolan II is the subject matter that is cited in support of the rejection of claims under § 103(a).

> I claim:
> 1. A method for in vitro screening for a transdominant intracellular bioactive agent capable of altering the phenotype of a cell, said method comprising the steps:
> a) introducing a molecular library of randomized candidate nucleic acids into a plurality of cells, wherein each of said nucleic acids comprises a different nucleotide sequence, wherein said randomized candidate nucleic acids are expressed in said cells to produce a plurality of randomized peptides;
> b) screening said plurality of cells for a cell exhibiting an altered phenotype, wherein said altered phenotype is due to the presence of a transdominant bioactive agent.